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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/732,813	12/11/2003	Kamehameha Kay-Min Wong JR.	1954-381	9416

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EXAMINER

CARLSON, KAREN C

ART UNIT PAPER NUMBER

1653

DATE MAILED: 12/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/732,813

Applicant(s)

WONG ET AL.

Examiner

Karen Cochran Carlson, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>7/19/04</u> . | 6) <input type="checkbox"/> Other: _____ |

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Applicant's election with traverse of Invention I, Claims 1-11, in the reply filed on October 3, 2005 is acknowledged. The traversal is on the ground(s) that the methods of Invention IV uses the fusion protein of Invention I. Also, that the DNA encoding the fusion protein (Invention II) be joined with the method of using the DNA encoding the fusion protein (Invention III). Upon search and reconsideration of the issues, it appears that there is allowable subject matter in Invention I; therefore, the Examiner has rejoined all Inventions and Claims 1-16 have been examined.

Priority is to December 11, 2002.

The disclosure is objected to because of the following informalities:

Table III at page 27+ describes nucleic acid sequences. These sequences are considered to be figures, and should be set forth in the drawings and not in the figures. Alternatively, Table III can be removed and reference made to the paper and/or computer readable form of the sequence listing using sequence identification numbers.

The specification is somewhat confusing because reference is made to protein when nucleic acid appears to be intended. For example, at page 7, in para. [00023], the sentence "A variety of exemplary RepVP22 fusion constructions were constructed in which AAV rep or fragments thereof were linked in frame to the N- or C-terminus of VP22 within an expression plasmid (Invitrogen)". Proteins are not placed in plasmids. Thus, Applicants should re-word this sentence to read, for example: A variety of exemplary RepVP22 DNA fusion constructions were constructed in which nucleic acid encoding AAV rep or fragments thereof were linked in frame to nucleic acid encoding the N- or C-terminus of VP22 within an expression plasmid (Invitrogen). The above referenced sentence is only an example of how the specification misrepresents the proteins versus the nucleic acids. Thus, Applicants are required to review their specification and

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amend the specification to more clearly point out if reference is being made to protein or to nucleic acid.

The Brief Description of the Drawings do not refer to each figure. For example, there is no Figure 3 but there are Figures 3A and 3B. Thus, at page 4, para. [00011], "Figure 3 is a cartoon" should be amended to recite — Figure 3A and 3B are cartoons...—. See also Figures 6A-C, 7A-E, and 8A-B.

Appropriate correction is required.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In Claims 1, 2, 14, 15, and 16, the full name for the acronyms should be provided.

In Claims 5-8, the reference sequence identification number should be provided, that is, the specific Rep protein is not set forth, nor is the reference SEQ ID NO. Thus, it is not clear what is meant if the carboxyl terminal amino acids are truncated at amino acid residue 492. Further, while the specification does not describe the Rep proteins in any detail, USP 6,627,617 states that Rep78 and Rep68 are essentially identical except for a unique carboxy termini generated from unspliced (Rep78) and spliced transcripts (Rep68) while Rep52 and Rep40 are amino terminal truncations of Rep78 and Rep68, respectively (col. 1, lines 48-55). Thus, without a reference sequence one skilled in the art cannot know what is meant if the carboxyl terminal amino acids are truncated at amino acid residue 492.

In Claim 11, it is not clear how many amino acids will be used as a spacer because the term "about" is indefinite.

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Claim 14 is indefinite because, first, the DNA construct of Claim 13 is not a rep-depleted rAAV vector as implied by the language used; second, it is not the DNA construct that provides the site-specific integration of a rep-deleted rAAV vector into the genome of a cell but its encoded fusion polypeptide product; and third, the rep-deleted rAAV vector is not integrated into a cell, but its genome. See also Claims 15 and 16 for similar language.

Claim 15 is indefinite because there appears to be a lack of steps. It appears that the rep-deleted rAAV vector and DNA construct of Claim 13 should be transfected into a cell and the DNA construct of Claim 13 expressed to form the encoded fusion polypeptide.

Art of record:

The closest art of record appears to be the teachings of Antoni et al (1991; J. Virology 65(1): 396-404). Antoni et al. teach plasmids pHIVrep comprising nucleic acid encoding both HIV-1 tat and Rep68/78. This teaching distinguishes over the claimed invention because the nuclear localization signal sequence in Rep68/78 is intact.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Cochran Carlson, Ph.D. whose telephone number is 571-272-0946. The examiner can normally be reached on 7:00 AM - 4:00 PM, off alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in cursive script that reads "Karen Cochrane Carlson" followed by a stylized "Ph.D.".

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER